

International Dairy Foods Association

Milk Industry Foundation

National Cheese Institute

International Ice Cream Association

June 15, 2004

Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane
Room 1061
Rockville, MD 20852

Re: Docket No. 2003N-0338 Obesity; Net Carbohydrate Claims

The International Dairy Foods Association (IDFA) offers these comments regarding “net carbohydrate” (“net carb”) labeling, a topic of great importance that is currently under consideration by the Food and Drug Administration (FDA). IDFA is the Washington, D.C.-based organization representing the nation's dairy processing and manufacturing industries and their suppliers. IDFA is composed of three constituent organizations: the Milk Industry Foundation (MIF), the National Cheese Institute (NCI), and the International Ice Cream Association (IICA). Its 500-plus members range from large multinational corporations to single-plant operations, and represent about 80% of the dairy products consumed in the United States.

FDA has announced that it will develop principles for use of the term “net” in relation to the carbohydrate content of food. IDFA applauds this effort, and supports development of “net carb” guidelines that will help to ensure that all “net carb” claims are truthful and not misleading. IDFA members believe strongly that “net carb” claims, if used properly, are permitted under the Federal Food, Drug, and Cosmetic Act (FFDCA), and convey scientifically-grounded information that is important to consumers who wish to control carbohydrate intake.

Properly Positioned “Net Carb” Claims Are Lawful and Permitted Under the FFDCA

Properly positioned “net carb” claims have two essential elements: (1) a purely factual statement, in grams per serving, of the amount of “net” carbohydrate in the food—i.e., the carbohydrate that may reasonably be expected to have a significant effect on blood glucose level; and (2) an explanation, if necessary, of the basis upon which the “net carb” count is calculated. Proper “net carb” claims do not “characterize” the level of a nutrient in food, and thus are not required to be the subject of a nutrient content claim definition issued pursuant to section 403(r) of the FFDCA, nor are factual declarations of this type subject to any other express prohibition. Accordingly, so long as “net carb” claims are presented in a truthful and not misleading manner, they may be used in food labeling in full compliance with the FFDCA and applicable FDA requirements.

The dairy industry provides “net carb” counts for a variety of products that may be useful to consumers seeking to control carbohydrate intake, and is committed to do so in a responsible manner. For example, to ensure that consumers understand the relationship between the “net carb” declaration and the Nutrition Facts box, one IDFA member provides the following explanation of the basis for a purely factual “net carb” count:

NET CARBS CALCULATION: For those watching their carbs, net carbs are calculated by taking the grams of total carbohydrates and subtracting the grams of fiber and the grams of sugar alcohol, since these have little impact on blood sugar levels.

In another product, marketed as a dairy beverage, the “net carb” count of 3 grams matches the declaration of Total Carbohydrate in the Nutrition Facts box, since dietary fiber and sugar alcohols are not present in the food.

These examples reflect merely two of the many instances in which “net carb” claims are made in a truthful and not misleading manner. IDFA urges FDA to recognize, as it develops “net carb” guidelines, that flexibility is critical to ensure that truthful and not misleading claims are not inadvertently restricted. A one-size-fits-all approach cannot possibly take into account the multitude of products for which “net carb” labeling may be appropriate. For example, for products for which the “net carb” count equals the Total Carbohydrate count in the Nutrition Facts box, a detailed explanation of the basis for the “net carb” number may not be necessary.

“Net carb” Claims Are Based Upon Meaningful Differences Among Carbohydrates and Are Grounded in Sound Science

Properly positioned “net carb” claims are based on valid scientific principles regarding differences among carbohydrates. “Net carb” claims that are properly substantiated are, therefore, truthful and not misleading.

Although all carbohydrates share certain chemical characteristics, it is well recognized that the rate and manner in which different types of carbohydrates may be digested, absorbed, and metabolized may differ considerably.^{1/} Some carbohydrates are digested and absorbed rapidly into the bloodstream, leading to a noted peak in blood glucose concentration. Other carbohydrates, such as fiber, may resist digestion in whole or in part. There are other carbohydrates, that are absorbed slowly and have very little impact on blood sugar levels.

^{1/} See, e.g., National Academy of Sciences, Institute of Medicine, Dietary Reference Intakes: Energy, Carbohydrate, Fiber, Fat, Fatty Acids, Cholesterol, Protein, and Amino Acids, at 6-3 (2002) (prepublication copy) (addressing glycemic response); Foster-Powell, J. et al., International table of glycemic index and glycemic load values: 2002, *Am. J. Clin. Nutr.* 2002; 76:5-56; Food and Agriculture Organization (FAO) Food and Nutrition Paper 66, Carbohydrates in Human Nutrition.

“Net carb” claims help consumers to distinguish carbohydrates that do not have a significant glycemic effect from those that do. In addition, some carbohydrates provide different caloric levels than others, which also could be a relevant basis for “net carb” statements. Therefore, there may be various reasonable bases for such statements, including the caloric contribution of different carbs and the effect of different carbs on the blood sugar level.

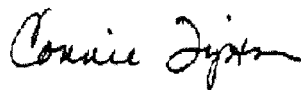
Fanciful Names and Terms that are Descriptive, but Do Not Characterize, Carbohydrate Content Are Likewise Permitted

Like “net carb” claims, fanciful names and similar terms (e.g., “Carb Countdown™,” “Carb Freedom™,” and “Carb Control™”) are used to highlight products that have been reformulated in carbohydrate content or that may feature a desirable carbohydrate profile. Such brand names should not be interpreted as implied nutrient content claims particularly if the food is clearly represented as a food for special dietary use. These fanciful names suggest that a product may be useful to individuals on carbohydrate-restricted diets or to consumers seeking a specific level of carbohydrate intake (e.g., by avoiding refined sugars or by emphasizing fiber intake). Unless the term “low carbohydrate” is included, however, such names and terms do not imply that a food *per se* is “low carbohydrate.”

For example, a term such as “Carb Countdown™” would be of interest and value to consumers who count carbohydrate grams as part of an overall carbohydrate-restricted diet, but it says nothing to characterize the product itself as “low carbohydrate.” Accordingly, unless fanciful and similar terms expressly include “low carb” or variations thereof (e.g., “lo”), which are nutrient content claims subject to FDA definition, they are lawful so long as they are not false or misleading in any particular.

In summary, “net carbohydrate claims,” if presented properly, are truthful and not misleading statements that are of great interest to many consumers. IDFA urges FDA to develop flexible guidelines that acknowledge the lawfulness of such claims, and provide sound guidance concerning their use.

Sincerely,

A handwritten signature in black ink, appearing to read "Connie Tipton". The signature is fluid and cursive, with the first name being more prominent.

Connie Tipton
President and CEO